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10/764,010	01/22/2004	Eugene J. Alexander	3104/109	8938

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EXAMINER	
CWERN, JONATHAN	
ART UNIT	PAPER NUMBER
3737	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/764,010	ALEXANDER ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-22 and 34-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-22 and 34-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/15/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 1, 3-22, and 34-93 are objected to because of the following informalities:

In claim 1, line 3, "said joint" lacks antecedent basis. In claim 3, it is unclear if this is the same cartilage referred to in claim 1. In claims 4 and 12, it is unclear how "therapy" comprises "an implant, a replacement material, a scaffold, a regenerating material, or a repair system". In claim 5, "said diseased tissue" lacks antecedent basis. In claims 6, 8, 9, 14, 16, 17, and 62, in view of the recitation of "is used to..." it is unclear as to what further step of the method has been positively set forth. In claim 8, "said diseased tissue" and "said normal cartilage" lack antecedent basis. In claim 10, the last sentence ends in a comma and period, the comma should be removed. In claim 11, "said normal cartilage" lacks antecedent basis. In claim 12, "said technique" lacks antecedent basis. In claim 13, "said diseased tissue" lacks antecedent basis. In claim 16, "said diseased tissue" and "said normal cartilage" lacks antecedent basis. In claim 18, the word "said" should be inserted between "wherein physical" to remain consistent with the other claims. Claims 34 and 63 refer to bone, this appears inconsistent with claims 1 and 10. It is unclear how "determining a therapy" differs from "selecting a therapy" in claim 35. In claims 42 and 43, "the normal cartilage" lacks antecedent basis. In claims 44 and 46, "said model" should be "said physical model". In claim 82, "the subchondral bone" lacks antecedent basis. In claim 84, "the inner cartilage surface" lacks antecedent basis. In claim 87, line 4, "or" is misspelled. On line 6, "the" should be

inserted before "three-dimensional". On line 7, remove "and". In claim 93, "the inner cartilage surface" lacks antecedent basis.

Appropriate correction is required.

The claims contain a large amount of errors. Applicant is advised to carefully check the language of all the claims to ensure that they are now correct.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-22, and 34-93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 94-293 of U.S. Patent No. 7239908. Although the conflicting claims are not identical, they are not

patentably distinct from each other because different types of electronic evaluation are obvious modifications.

Claims 1, 3-22, and 34-93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 7184814. Although the conflicting claims are not identical, they are not patentably distinct from each other because determining the margin between normal and diseased tissue is an obvious modification when analyzing a degenerative joint.

Claims 1, 3-22, and 34-93 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-120 of copending Application No. 11/769434. Although the conflicting claims are not identical, they are not patentably distinct from each other because obtaining information about the volume is an obvious modification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-22, and 34-93 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 69-72, and 75-89 of copending Application No. 09/882363. Although the conflicting claims are not identical, they are not patentably distinct from each other because obtaining information about the biomechanical data is an obvious modification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-22, and 34-93 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-114 of copending Application No. 11/739326. Although the conflicting claims are not identical, they are not patentably distinct from each other because utilizing an implant for the treatment is an obvious modification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-22, and 34-93 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 11/678763. Although the conflicting claims are not identical, they are not patentably distinct from each other because determining the margin between normal and diseased tissue is an obvious modification when analyzing a degenerative joint.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-22, and 34-93 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23

of copending Application No. 11/410515. Although the conflicting claims are not identical, they are not patentably distinct from each other because determining the axes related to the joint is an obvious modification

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, and 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of claim 1 refers to cartilage, however, the body of the claim refers to cartilage or subchondral bone surface.

Claims 1, 3-22, and 34-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 3-22, and 34-86 are incomplete because the claims are directed to a method of treating, however, no steps of treatment have been positively set forth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5, 7, 10-11, 13, 15, 34-36, 48-50, 62-63, 79, and 87-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delp et al. (US 5682886) in view of Aouni-Ateshian et al. (US 6161080) and Paul et al. (US 5320102).

Delp et al. show a system for joint replacement surgery. The system processes medical image data to build a 3D computer model of the patient's leg, and align, size, and place a prosthetic component (column 8, lines 5-31). The three-dimensional geometry of the joint is analyzed to determine the required dimensions and geometry of the prosthesis. A number of points are selected in the 3D surface reconstruction of the joint and prosthesis (column 9, line 19-column 11, line 5). Selecting points in three-dimensional space in order to develop the proper dimensions and geometry of a three-dimensional object would inherently include determining three non-coplanar points. Points would be selected on the different bones of the joint, such as in the case of a

knee joint, the lateral or medial femoral condyle (column 7, lines 38-52). A variety of different imaging modalities can be used to obtain the data (column 8, lines 32-61). The biomechanical information, such as the biomechanical axes, is obtained (column 11, lines 49-59) and used when designing the model, as well as anatomical information such as anatomical landmarks (column 11, lines 25-27). When planning the design of the prothesis, the contact surfaces are accounted for as well (column 14, lines 1-42). By utilizing constraints, both static and dynamic alignment are accounted for, in order to ensure that there is equal contact throughout the range of motion and to prevent the ligaments from being too tight in extension. Estimating for normal gait is an obvious modification, as gait is a typical unconstrained movement, and would be accounted for when ensuring equal contact throughout the range of motion.

Aouni-Ateshian et al. disclose a method of generating a three-dimensional representation of one or more anatomical joints. Aouni-Ateshian et al. teach that cartilage topography and thickness can be reconstructed, and geometric data needed for a model can be obtained (column 37, line 65-column 8, line 25).

When designing a model to analyze an object, it is typical to design the model as close to the real object as possible, in order to accurately analyze what would happen to the real object. Therefore, it is obvious that the physical model would reflect the patient's anatomy, such as the geometry and thickness of the normal and diseased cartilage, and the inner and outer surfaces, and the subchondral bone.

Paul et al. disclose a method of treating a human with diseased cartilage in a joint. Pault et al. teach a method of treating a human with diseased cartilage in a joint

(abstract), which method comprises: utilizing an MRI scan to generate a cross-sectional electronic image of said joint (column 4, lines 1-55), wherein said image includes both normal and diseased cartilage (column 10, lines 55-65); and utilizing information from said image to create a geometric model of an area of diseased cartilage (the MR cartilage image is a model, column 4, lines 55-65), wherein said geometric model is used in selecting a treatment of said diseased cartilage (column 11, lines 35-55); electronically evaluating the image of the joint to determine the thickness or biochemical content (column 4, lines 1-10, and column 5, line 65-column 6, line 5); obtaining a three-dimensional map (the MR cartilage image is a three-dimensional map, column 4, lines 55-65); determining the margins of the diseased cartilage in relation to the normal cartilage based on the thickness or biochemical contents, allowing for the area of diseased cartilage to be calculated (the MRI scan of the joint allows for the total cartilage surface area to be determined, knowledge of the margins of the diseased area will then allow for a calculation of the total area of the joint containing diseased cartilage, column 10, lines 55-65). Also, estimating the change in thickness of a region of the cartilage over time to determine a change in thickness between a first time and a second time, to determine the amount of degeneration in the cartilage (column 11, lines 5-55); the therapy includes an agent that stimulates repair of diseased tissue (column 11, lines 45-55); the MRI technique obtains a series of two-dimensional views reconstructed to a three-dimensional image (implicit with MR imaging); the MRI technique employs gradient or spin echo (column 4, lines 25-40). Data transmission throughout a computer system is well known in the art, any part of the computer can be

considered a "site" or the receiving or transmitting device, and the term "located distant" can refer to any distance.

Delp et al. mainly discuss the bones when discussing joint replacement surgery, however cartilage must be considered as well when analyzing a patient's joint. It would have been obvious to one of ordinary skill in the art to have applied the same teachings of Delp et al. to the cartilage as well as the bone, as taught by Aouni-Ateshian et al. This will allow for a better implant to be developed for the joint replacement.

It would have been obvious to one of ordinary skill in the art, to analyze the degenerative cartilage in the patient and to have determined a therapy based on the cartilage information as taught by Paul et al., in a joint replacement technique as taught by Delp et al., in order to better develop a proper implant.

Claims 4, 6, 8-9, 12, 14, 16-19, 21-22, 37-47, 51-57, 59-61, 64-78, and 80-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delp et al. (US 5682886) in view of Aouni-Ateshian et al. (US 6161080) and Paul et al. (US 5320102) as applied to claims 1, 7, and 10 above, and further in view of Goldberg et al. (US 6835377).

Goldberg et al. disclose a method for repair of degenerative cartilage. Goldberg et al. teach that the therapy can comprise osteotomy or an autologous chondrocyte transplantation (it is well known to perform osteotomy, column 1, lines 40-50, also the method used in the invention uses autologous mesenchymal stem cells supported by a three-dimensional scaffold, which is implanted in the body, column 3, lines 1-25).

It would have been obvious to one of ordinary skill in the art, to have implanted a device as taught by Goldberg et al. in place of the prosthesis implanted by Delp et al. in order to aid in repairing the degenerated cartilage.

Claims 20 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delp et al. (US 5682886) in view of Aouni-Ateshian et al. (US 6161080), Paul et al. (US 5320102), and Goldberg et al. (US 6835377) as applied to claims 8 and 16 above, and further in view of George, III et al. (US 6175655).

George, III et al. disclose a method for manipulating 3D MRI data to view internal body structure. George, III et al. teach the use of 3D Euclidean distance values in manipulating the 3D MRI data (table of column 8-column 9 shows a variable used which is Euclidean distance between points).

The Euclidean distance is a well known technique to calculate the distance between two points, and could be used when constructing the 3D model.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-22, and 34-93 have been considered but are moot in view of the new ground(s) of rejection.

It should be noted that applicant has removed the limitation of "normal and diseased cartilage" from claims 1 and 10. It should be noted that when amending claim 8 to fix lack of antecedent basis problems, that claims 38-43 depend from claim 8, which

contains the limitation of normal cartilage, and so they have not been objected or rejected in regards to this problem.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. G. C./
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737